



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/799,094

03/12/2004

Lixiao Wang

1001.2350101

7638

28075 7590 04/29/2009
CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

04/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,094	Applicant(s) WANG ET AL.	
	Examiner ELLSWORTH WEATHERBY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 9, 12, 24-25, 27, 32-34, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillies et al. (USPN 6,272,370).

4. Gillies et al. (hereinafter Gillies) teaches a medical device, comprising: a biocompatible polymeric body (col. 24, ll. 13-31; col. 25, ll. 12-53), and an attachable marker band secured circumferentially to an outer surface of the biocompatible body (col. 25, ll. 12-53; Fig. 1, refs. 6; Fig. 4b), the marker including a fluoroscopic imaging enhancement material and MRI enhancement material in separate concentric and non-

circumferentially contiguous layers (col. 25, ll. 12-53; col. 29, ll. 16- 20; Fig. 1, refs. 6; Fig. 4b). Gillies also teaches that the biocompatible body comprises a material selected from the group consisting of metal, ceramic, autogeneous material, biologically derived materials and combinations thereof (col. 27, ll. 59-63; col. 28, ll. 27-30). Gillies also teaches the use of drug coatings (col. 20, l. 31- col. 21. l. 65).

5. Claims 39-44, 46-47, 54, 56, 59, 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Stinson et al. (Pub. No.: 2005/0131522).

6. Stinson teaches a markings system for use with a medical device (e.g. catheters, guidewire, medical coils, pacer leads and vascular stents) to mark a region thereof (abstract; 0025), comprising: a marker band that is circumferentially attachable to an outer surface of the medical device, the marker including a fluoroscopic imaging enhancement material and an MRI enhancement material (0025; 0043; 0057; 0059; 0061; 0067; 0071; Fig. 1; Ref. 26); wherein the fluoroscopic imaging enhancement material is provided in a first layer and the MRI enhancement material is provided in a second layer, wherein the first and second layers are concentric with each other and are bonded, wherein each of the first and second layers is non-circumferentially contiguous (0025; 0043; 0057; 0059; 0061; 0067; 0071; Fig. 1; Ref. 26). Stinson also teaches that the fluoroscopic enhancement material may be a pure metal (0057). Stinson also teaches disposing the fluoroscopic imaging enhancement material and the MRI enhancement material in a polymer matrix (0076).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-6 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Bavaro (Pub. No.: 2005/0255317).

9. Gillies teaches all the limitations of the claimed invention except for expressly teaching that the marker is secured by adhesive, friction, or shrink material. Gillies also does not expressly teach that multiple markers are secured to the biocompatible body at locations indicative of the location of a balloon carried by the balloon catheter.

10. In a related field of endeavor, Bavaro et al. (hereinafter Bavaro) teaches a medical device, comprising: a biocompatible body (0005), and an attachable marker band secured circumferentially to an outer surface of the biocompatible body (0015). Bavaro goes on, teaching that the marker is secured by adhesive or friction or shrink material (0015-0016; 0023; 0035; 0048-0049). Bavaro also teaches multiple markers are secured to the biocompatible body at locations indicative of the location of a balloon carried by the balloon catheter (0005; 0016; 0018).

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the fluoroscopic and MR-visible device of Gillies in view of the marker attachment means of Bavaro. The motivation to modify the fluoroscopic and

MR-visible device of Gillies in view of the marker attachment means of Bavaro would have been to secure markers to a member using well known securing means, including those disclosed by Bavaro.

12. Claims 7-8, 10-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Aita et al. (USPN 6,884,234 B2).

Gillies teaches all the limitations of the claimed invention except for expressly teaching that the marker includes multiple layers. Gillies also does not expressly teach that the marker band includes three or more layers. Gillies also does not expressly teach that a first layer includes a fluoroscopic imaging enhancement material and a second layer has a MRI enhancement material and a third layer. Gillies also does not expressly teach that the third layer is in contact with the biocompatible body. Gillies also does not expressly teach that the third layer is between the first and second layers. Gillies also does not expressly teach that the third layer defines an exterior surface of the marker.

In the same field of endeavor, Aita et al. '234 (hereinafter Aita) teaches a plurality of layers where separate layers are provided for each imaging enhancement material (col. 3, ll. 1-13). Aita further teaches that a third layer that acts as a spacer between the first and second layers (col. 3, lines 1-13). Aita goes on, teaching a plurality of imaging layer combinations (col. 3, l. 14- col. 4, l. 4). Aita also teaches that the imageable layers should have a thickness of about .0005 inch to 0.01 inch (col. 3, ll. 1-13). Aita also

provides a plurality of imageable layers disposed between outer and inner layers (col. 4, l. 65- col. 5, l. 11).

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the fluoroscopic and MR-visible device of Gillies in view of the layered markers of Aita. The motivation to modify the fluoroscopic and MR-visible device of Gillies in view of the layered markers of Aita would have been to improve the structural or material properties of the marker, as taught by Aita.

14. Claims 17-18, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Dor et al. (USPN 6,334,871 B1).

Gillies teaches all the limitations of the claimed invention except for expressly teaching that the MRI imaging enhancement material has a radiopacity of 0.9 or less than the radiopacity of steel and that the MRI enhancement material has an atomic number of 40 or less. Gillies also does not expressly teach that the radiopacity is about 1.1 times more than stainless steel. Gillies also does not expressly teach that the MRI visibility is greater than about 280mg/ml gadodiamine in 5000 ml blood.

In the same field of endeavor, Dor et al. '871 (hereinafter Dor) teaches using a material with radiopacity similar to steel to enhance or decrease radiopacity compared steel (claim 1, claim 5). Dor also teaches using a cobalt-chromium alloy (claim 13). Regarding claim 22, the examiner is interpreting the limitations of the claim to be met because Dor claims several relative visibilities and it is obvious variation to determine the visibility of device relative to any available and well-known medical product including

having a visibility about equal or greater than about 280 mg/ml gadodiamine in 5000 ml blood.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gillies in view of Dor. The motivation to modify Gillies in view of Dor would have been to use a material in varying thickness that would have less radiopacity than steel to improve imaging or visibility of the device.

15. Claims 19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Dor et al. (USPN 6,334,871 B1) as applied to claim 17 above, and further in view of MacDonald et al. (Pub. No.: 2007/0093142).

Gillies in view of Dor teaches all the limitations of the claimed invention except for expressly teaching that the marker includes multiple layers and wherein the layers have a thickness of about 1 micron or less.

In the same field of endeavor, MacDonald et al. '142 teaches coating a ring or a catheter with a layer that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gillies in view of Dor with MacDonald et al. '142. The motivation to modify Gillies in view of Dor with MacDonald et al. '142 would have been to minimize the layer's interaction with the surrounding environment, as taught by MacDonald et al. '142 [0175].

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of MacDonald et al. (Pub. No.: 2007/0093142).

Gillies teaches all the limitations of the claimed invention except for expressly teaching that the marker includes multiple layers and wherein the layers have a thickness of about 0.005 inch or less. Gillies also does not expressly teach that the MRI enhancement material is present at 25% or less by weight of fluoroscopic imaging enhancement material.

In the same field of endeavor, MacDonald et al. '142 (hereinafter MacDonald) teaches facilitating MRI compatibility of a device by minimizing the amount of coated MRI enhancing material where the coating layer that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of MacDonald et al. '142. The motivation to modify Griffin in view of MacDonald et al. '142 would have been to minimize the layer's interaction with the surrounding environment, as taught by MacDonald et al. '142 [0175].

17. Claims 23, 28-31, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Stinson et al. (Pub. No.: 2005/0131522).

18. Gillies teaches all the limitations of the claimed invention except for expressly teaching the fluoroscopic imaging material has a density of about 9.9g/cc or more. Gillies also does not expressly teach that the MRI material is gadodiamine, dysprosium

terbium and alloys, oxides and mixtures thereof. Although Gillies teaches that the marker extends at least 50% of the circumference of the body, Gillies does not expressly teach that the fluoroscopic imaging material and MRI material are arranged concentrically with respect to one another. Gilles also does not expressly teach that the device is a guidewire.

19. In a related field of endeavor, Stinson et al. (hereinafter Stinson) teaches a medical device or guidewire with multiple layers or coatings, where the individual layers may comprise MR enhancing materials and fluoroscopic layers that extends over 70 to 85% of the circumference of the body (abstract; 0022; 0057; 0067; Fig. 1; ref. 26).

Stinson also teaches a fluoroscopic enhancement material having a density of about 9.9g/cc or more (0057). Stinson further teaches a MRI material that comprises gadodiamine, dysprosium terbium and alloys, oxides and mixtures thereof (0067).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gillies in view of Stinson. The motivation to modify Gillies in view of Stinson would have been to improve radiopacity or MR imaging using any of the known material compositions, including the material disclosed by Stinson.

21. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of Kucharczyk et al. (USPN 6,026,316).

Stinson teaches all the limitations of the claimed invention except for expressly teaching that the MRI enhancement material is disposed within a ceramic matrix.

Kucharczyk et al. '316 (hereinafter Kucharczyk) teaches using MR visible ceramics in a catheter (col. 4, lines 16-35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of Kucharczyk et al. '316 to facilitate the use of device in the presence of strong MRI fields.

22. Claims 48-51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of MacDonald et al. (Pub. No.: 2007/0093142).

Stinson teaches all the limitations of the claimed invention except for expressly teaching that the marker includes 4-20 layers and wherein the layers have a thickness between about 0.00005 inches and about 0.005 inches. Stinson also does not ex

In the same field of endeavor, MacDonald et al. '142 teaches coating a ring or a catheter with multiple layers, where a layer that has a thickness between about 0.00005 inches and about 0.005 inches [0175]. MacDonald also teaches that the marker band includes an inward-facing projection [0173-0176; Fig. 56].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of MacDonald. The motivation to modify Gillies in view of MacDonald would have been to minimize the layer's interaction with the surrounding environment, as taught by MacDonald [0175].

23. Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of MacDonald et al. (Pub. No.: 2007/0093142) as applied to claim 48 above, and further in view of Devens et al. (Pub. No.: 2005/0124976).

Stinson in view of MacDonald teaches all the limitations of the claimed invention except for expressly teaching that the marker includes a drug layer.

In the same field of endeavor, Devens teaches a plurality of internal medical devices comprising fluoroscopic and MRI markers in one or more separate layers [0062]. Devens also teaches a bonding layer [0007] and a drug delivery layer [0061].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of MacDonald with Devens. The motivation to modify Stinson in view of MacDonald with Devens would have been to provide multiple functions for each band using well known multiple layered medical devices, as shown by Devens.

24. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of Zhong et al. (Pub. No. 2004/0186377).

25. Stinson teaches all the limitations of the claimed invention except for expressly teaching that the marker securing comprises crimping the marker onto the medical device.

26. In a related field of endeavor, Zhong et al. teaches a means for attaching a member to a medical device, where the member may comprise a marker (abstract; 0049). Zhong goes on, teaching crimping a member onto the medical device (0035).

27. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of the attachment means of Zhong. The motivation to modify Stinson in view of the attachment means of Zhong would have been to use any known means for attaching a marker to a device, including the crimping of Zhong.

28. Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of Bavaro (Pub. No.: 2005/0255317).

29. Stinson teaches all the limitations of the claimed invention except for expressly teaching that the marker is secured by adhesive, friction, or shrink material.

30. In a related field of endeavor, Bavaro et al. (hereinafter Bavaro) teaches a medical device, comprising: a biocompatible body (0005), and an attachable marker band secured circumferentially to an outer surface of the biocompatible body (0015). Bavaro goes on, teaching that the marker is secured by adhesive or friction or shrink material (0015-0016; 0023; 0035; 0048-0049). Bavaro also teaches multiple markers are secured to the biocompatible body at locations indicative of the location of a balloon carried by the balloon catheter (0005; 0016; 0018).

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the fluoroscopic and MR-visible device of Stinson in view of the marker attachment means of Bavaro. The motivation to modify the fluoroscopic and

MR-visible device of Stinson in view of the marker attachment means of Bavaro would have been to secure markers to a member using well known securing means, including those disclosed by Bavaro.

32. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of Dor et al. (USPN 6,334,871 B1).

Stinson teaches all the limitations of the claimed invention except for expressly teaching that the medical device has a radiopacity less than stainless steel.

In the same field of endeavor, Dor et al. '871 (hereinafter Dor) teaches using a material with radiopacity similar to steel to enhance or decrease radiopacity compared steel (claim 1, claim 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of Dor. The motivation to modify Stinson in view of Dor would have been to use a material in varying thickness that would have less radiopacity than steel to improve imaging or visibility of the device.

33. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (USPN 6,272,370) in view of Ishii (Pub. No.: 2003/0163117).

Gillies teaches all the limitations of the claimed invention except for expressly teaching that the marker is C-shaped.

In the same field of endeavor, Ishii '117 (hereinafter Ishii) teaches using C-shaped markers [0082].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gillies in view of Ishii. The motivation to modify Griffin in view of Ishii would have been to use any known marker shape to facilitate secure attachment and enhanced visibility upon the medical device.

34. Claims 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. (Pub. No.: 2005/0131522) in view of Ishii (Pub. No.: 2003/0163117).

Stinson teaches all the limitations of the claimed invention except for expressly teaching that the marker is C-shaped.

In the same field of endeavor, Ishii '117 (hereinafter Ishii) teaches using C-shaped markers [0082].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stinson in view of Ishii. The motivation to modify Stinson in view of Ishii would have been to use any known marker shape to facilitate secure attachment and enhanced visibility upon the medical device.

Response to Arguments

35. Applicant's arguments, filed 12/11/2008, with respect to the applicability of Griffith et al. (Pub. No. 2004/0193140) as prior art have been fully considered and are persuasive. The 07/02/2007 Non-Final Rejection of claims 1-64 has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768